

DOCKET NO.: CARP-0085  
Applicati n No.: 09/647,331  
Office Action Dated: April 9, 2003

PATENT

### REMARKS/ARGUMENTS

Applicants and applicants' representative gratefully acknowledge the interview conducted with Examiners Ostrup and Klass on September 9, 2003. Applicants appreciate the Examiners' input and helpful comments during the interview.

Reconsideration of the present application in view of Applicants' interview and the following remarks is respectfully requested. In an office action mailed April 9, 2003, claims 1-15, 18-35, and 38-55 were rejected.

#### Status of the Claims

Claims 1-15, 18-35, and 38-55 are currently pending in the present application. Claims 11, 20, 22, 24, and 33 have been amended. No new matter has been introduced.

#### Claim Amendments

Claims 11, 20, and 22 have been amended to correct grammatical errors and/or more clearly define the claimed invention.

Claims 24 and 33 have been amended to reflect that, upon aerosolization of the claimed composition, the first (medicament) and second particulate materials segregate into a respirable first fraction and a non-respirable second fraction. Support for these amendments may be found in the specification as originally filed at, *inter alia*, page 2, lines 5-9, and page 8, lines 5-12.

**Claim Rejections Under 35 U.S.C. §102(b)**

Claims 1-5, 12-15, 18-23, 25-32, 34-35, and 39-55 have been rejected under 35 U.S.C. §102(b) in view of Glaxo Group Limited WO 96/19968 ("Glaxo").

It was agreed during Applicants' interview with the Examiners on September 9, 2003 that Claim 1 is allowable over Glaxo, and that the rejection under 35 U.S.C. §102(b) of Claims 1-5, 12-15, 18-23, 34-35, and 39-55 is withdrawn because "the median aerodynamic diameter and median volume diameter of the smaller and larger particles, respectively, was not taught in the Glaxo reference" and "the functional limitation wherein the first and second materials are segregated upon aerosolization into a respirable first fraction and a non-respirable second fraction was not taught in the prior art." (Interview Summary dated September 9, 2003, paper no. 13.)

Accordingly, Applicants respectfully submit that claims 1-5, 12-15, 18-23, 34-35, and 39-55 are now in condition for allowance.

**Claim Rejections Under 35 U.S.C. §103**

Glaxo

Claims 6-11 have been rejected under 35 U.S.C. §103(a) as unpatentable over Glaxo. In light of the Examiner's indication in the interview on September 9, 2003 that Claim 1 is allowable over Glaxo, however, Applicants respectfully submit that claims 6-11, which depend from Claim 1, are also allowable over Glaxo.

Glaxo / Makino

Claims 1, 24, 33, and 38 have been rejected under 35 U.S.C. §103(a) as unpatentable over Glaxo in view of U.S. Patent No. 5,626,871 ("Makino").

The Examiner asserts that “the primary reference lacks the second particulate material of instant claims 24, 33, and 38.” (Office Action at page 8.)

The Examiner further asserts that Makino teaches “sugars, amino acids, and proteins as dispersion agents that can be used in aerosol formulations and that preparations for intratracheobronchial administration comprising medicaments with or without additives are formulated to particular sizes depending upon the region in the air way that the powder preparation is targeted.” (Id.)

To establish a *prima facie* case of obviousness, all of the claim limitations must be taught or suggested by the prior art. MPEP §2143.03 Neither Glaxo nor Makino, however, teach or suggest that the medicament and the second particulate material are segregated upon aerosolization into a respirable first fraction and a non-respirable second fraction, as described in claim 1 and presently amended claims 24, 33, and 38. Accordingly, Applicants respectfully submit that the present claims are not rendered obvious by Glaxo in view of Makino.

In addition to and separate from the above discussion, Applicants respectfully submit that the claims are not rendered obvious by Glaxo in view of Makino because Makino is not analogous prior art. “In order to rely on a reference as a basis for rejection of an applicant’s invention, the reference must either be in the field of the applicant’s endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned.” MPEP §2141.01(a), citing *In re Oetiker*, 977 F.2d 1443, 1446 (Fed. Cir. 1992). Makino is directed to the field of dry powder inhalers, (Makino at, *inter alia*, col. 2, lines 59-65) whereas the present invention is directed to formulations including a propellant for use in metered dose inhalers. (Specification at page 1.) It is well known in the art that these are

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separate endeavors. Additionally, Makino is not pertinent to the problems solved by the present invention. For example, the particle sizes of the particulate materials in the present invention serve to improve the suspension qualities and dispersion of the aerosol composition. (Specification at, *inter alia*, page 4, lines 6-10.) Makino is irrelevant to this goal because dry powder formulations do not include a propellant and therefore do not form suspensions. Therefore, Makino is not a suitable reference for use as a basis for the current rejection.

For all of the foregoing reasons, Applicants respectfully submit that claims 1, 24, 33, and 38 are not rendered obvious under §103 by Glaxo in view of Makino, and, accordingly, are now in condition for allowance.

### **Claim Rejections Under 35 U.S.C. §112**

Claims 11, 20, and 22 have been rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. Applicants respectfully submit that presently amended claims 11, 20, and 22 particularly point out and distinctly claim inventive subject matter and are, accordingly, now in condition for allowance.

### **Conclusion**

Applicants would again like to thank Examiners for their insights and comments in the interview of September 9, 2003. Enclosed for the record is the PowerPoint presentation used during that interview. Applicants have also submitted several journal articles referred to during the interview, listed in an Information Disclosure Statement filed herewith.

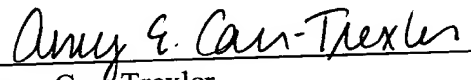
Applicants respectfully submit that the present application is now in condition for

**PATENT**

**DOCKET NO.:** CARP-0085  
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allowance. Reconsideration of the Office Action and an early Notice of Allowance are respectfully requested. In the event that the Examiner cannot allow the present application for any reason, the Examiner is encouraged to contact the undersigned to discuss resolution of any remaining issues.

Date: October 8, 2003

  
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